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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant: | G. Keren, et al. |
| Serial Number: | 09/839,643 |
| Filed: | April 20, 2001 |
| For: | Methods and Apparatus for Reducing Localized Circulatory System Pressure |
| Art Unit: | 3743 |
| Examiner: | Wieker, Amanda F. |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**AMENDMENT**

Sir:

Further to an office action dated February 24, 2006 applicants file the following remarks:

## REMARKS

The present application includes claims 49-51 and 59-111.

The claims were objected to due to an error in the references to paragraphs of the application providing their support. Applicants apologize for the error and the inconvenience to the Examiner. The error was due to use of an incorrect version of the application in which two of the paragraphs of the background of the application were mistakenly combined. Following is a corrected version of the listings of support corresponding to the application version from Jan 7, 2002, which includes paragraph numbers.

**Support**

Claims 59 and 84 find support at least on page 11, paragraph 24:

"In some embodiments, the valve will be chosen and designed so that it responds only upon certain conditions occurring within the heart, such as the following: absolute left atrial pressure, differential atrial pressure, other intra-cardiac pressures, other cardiovascular pressures, or other physiological conditions that might correlate to an exacerbated state of diastolic heart failure, such as blood oxygen saturation or pH."

on page 13, paragraph 26:

"Unlike the LVAD, however, the disclosed invention does not seek to significantly "support" the function of the left ventricle by pumping blood from the LV chamber to the body. Rather, it is intended only to "offload" the excessive pressure that builds through the diastolic phase of the cardiac cycle in some CBF patients. Whereas a normal LVEDP is in the range of 6-12 mmHg, patients with diastolic dysfunction heart failure (DDHF), end-diastolic pressure (EDP) in the left atrium (LA) and left ventricle (LV) can rise considerably above normal levels."

in paragraph 29 (page 12):

"in the event of an activation of the implanted device that corresponds to the significantly exacerbated state heart failure."

on page 16, paragraph 36:

"Thus for example, a chronic device can be a preventive device where when pressures rise for some reason to dangerous levels the pump goes into action and helps to lower the pressure in the left ventricle, thereby preventing the acute development of dyspnea and pulmonary edema and assures that the LVDP are always at an optimal level of no more than 15 mmHg."

and in the mention of mean LAP – mean RAP in paragraph 34 (page 13).

Claim 60 finds support at least in paragraph 37 (page 14) and in the passage "continuously moves a small amount of blood from the LV chamber to the aorta", in paragraph 25 (page 11). Claim 61 finds support at least in the first line of paragraph 27 (page 11). Claim 62 finds support at least in paragraph 28, second line, on page 12. Claim 63 finds support at least in paragraphs 30 and 31.

Claim 64 finds support at least in the end of paragraph 14 on page 7:

"For example in patients presenting with diastolic heart failure (DHF) the present invention prevents this occurrence by reducing diastolic pressures in the left atrium below the excessive levels that would otherwise have caused pulmonary edema."

Claim 65 finds support at least in paragraph 24, page 10. Claim 66 finds support at least in paragraph 14 (page 7). Claim 67 finds support at least in element 120 of Fig. 1, and paragraph 20. Claim 68 finds support at least in paragraph 20. Claim 69 finds support at least in paragraph 14: "a shunt-type device allows a small volume of blood to be released from the left ventricle to reduce the pressure.", as contrasts with paragraph 12: "The mechanical devices were built to allow propulsion of significant amount of blood (liters/min) and this is also their main technological limitation. The need for power supply, relatively large pumps and danger of hemolysis and infection are all of significant concern."

Claim 70 finds support at least in Figs. 1 and 5. Claims 71 and 72 find support at least in paragraph 34. Claim 73 finds support at least in paragraph 24. Claim 74 finds support at least in paragraph 35. Claim 75 finds support at least in paragraph 30. Claims 76-78 find support at least in Fig. 1. Claim 79 finds support at least in paragraph 21. Claim 80 finds support at least in pump 140 mentioned for example in paragraph 25. Claims 81-83 find support at least in paragraph 29.

Claims 85-86 and 89 and the amendment to claim 49, find support at least in paragraph 38. Claims 87 and 88 find support at least in paragraph 26. Claim 90 finds support at least in paragraph 25. Claim 91 finds support at least in paragraph 29. Claims 92 and 98 find support at least in paragraph 24. Claims 93-97 finds support at least in paragraph 28. Claim 99 find support at least in paragraph 35. Claim 100 finds support at least in the mention of mean LAP – mean RAP in paragraph 34. Claim 101 finds support at least in paragraph 18.

Claims 102 and 111 find support at least in paragraph 39 (page 15). Claim 103 finds support at least in paragraph 28 (page 12). Claim 104 finds support throughout the application in examples of measurement of absolute pressure. Claims 105 and 106 find support at least in paragraph 32. Claims 107 and 108 find support at least in paragraphs 36 and paragraph 9, respectively. Claims 109 and 110 find support at least in paragraph 28.

The amendment to claim 51 finds support at least in paragraph 35 (page 13).

**Conclusion**

In view of the above remarks, applicants submit that the claims are patentable over the prior art. Allowance of the application is respectfully awaited. If, however, the Examiner is not convinced and the Examiner is of the opinion that a telephone conversation may forward the present application toward allowance, applicants respectfully request that the Examiner call the undersigned at 1 (877) 428-5468. Please note that this is a direct *toll free* number in the US that is answered in the undersigned's Israel office. Israel is 7 hours ahead of Washington.

Respectfully submitted,
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